HIV Counseling and Testing Site Protocol

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CONFIDENTIALITY

Information gathered while counseling and testing individuals must be kept strictly confidential. Human Immunodeficiency Virus (HIV) test results should be kept in a locked file cabinet or password protected electronic format with access limited to personnel involved in counseling and testing. Counseling and testing must be conducted in an area where patient confidentiality and privacy can be assured. All efforts to ensure confidentiality at outreach events must be made. This includes, but is not limited to controlling the flow of traffic, spacing testing areas, transporting forms in a locked device, etc.

Health Insurance Portability and Accountability Act (HIPAA) guidelines and site-specific policies should always be followed. HIV counseling and testing sites are required to sign the Rules of Behavior with the Communicable Disease Surveillance Program related to PRISM data entry and client records.

Anonymous or Confidential Testing:

The Wyoming Department of Health (WDH) expects that all publicly sponsored counseling and testing sites offer confidential testing. Confidential testing facilitates linkage to follow-up counseling and referral for needed services and linkage to care after test results are received. Anonymous testing may impede the WDH's investigation following a reactive result and the ability to identify when an infection occurred.

INFORMED CONSENT

A separate consent form is not required for HIV testing and counseling. Sites can and are encouraged to incorporate HIV testing consent into the general consent form used. This helps normalize HIV testing as part of routine care. Additionally, opt-out consent that requires action to decline testing is preferred over more passive, opt-in, consents.

Minors (persons under 18 years of age) may receive services at Wyoming HIV counseling and testing sites without the knowledge or consent of their parent(s) or guardian(s). This protocol is designed for adolescents and adults and is dependent on the individual's capacity to understand the prevention messages and the ramifications of the results of the HIV test. Youth receive their results according to the protocol, and results are not shared with parents or guardians without freely-given, written consent of the adolescent.

Other situations such as language barriers and cognitive impairments may hinder obtaining informed consent. In these instances, use your best judgment and obtain consent from a translator or guardian if need be. It is not ethical to use a family member who accompanies a patient for testing to translate. Contact the Communicable Disease Unit (CDU) to coordinate necessary translation or interpretation services through our Language Line.

The patient must be provided the "Subject Information Notice" (found in each test kit box) and offered the chance to ask questions before specimen collection.

An HIV counselor may refuse to test an individual who: has expressed intent to harm themselves or others; is perceived to be under the influence of alcohol and/or other drugs; has expressed emotional instability; or has expressed an inability to comprehend HIV counseling and testing for any other reason(s). These clients may be referred to other resources as needed such as drug and alcohol programs, community hospitals, and mental health resources.

SCREENING

The Clearview Complete HIV 1 / 2 assay is a single use, point-of-care test used to detect antibodies to HIV Type 1 and Type 2. Used alone, the HIV antibody test cannot diagnose an HIV infection or Acquired Immunodeficiency Syndrome (AIDS).

State provided HIV tests may not be used at a publicly-sponsored site for generalized screening or as a precondition for employment, employee health, evidence of insurability, immigration, obtaining a marriage license, or admission to hospitals or schools. Counseling and testing sites are expected to adhere to the Centers for Disease Control and Prevention (CDC) 2006 Revised HIV Testing Guidelines (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm). Additionally, emphasis should be placed on risk based screening, which ensures thorough collection and discussion of patients' risk behaviors and testing needs. The WDH Communicable Disease Risk Assessment can be found here: http://health.wyo.gov/phsd/cds/index.html.

It is possible that individuals who are not part of high risk groups can become infected with HIV and would benefit from knowing their HIV status. For this reason WDH acknowledges the benefit to extending HIV screening beyond these high risk groups. Such screening should be considered on an individual basis.

Specific questions on WDH HIV Counseling and Testing Protocols should be brought to the Communicable Disease Prevention Program Manager (see Appendix A).

HEPATITIS SCREENING

The WDH recommends that HIV screening be accompanied by Hepatitis B and Hepatitis C screenings whenever risk factors overlap. A serum sample must be obtained for these tests. Hepatitis B antibody (HBsAb) testing should not be performed to determine vaccination status.

STANDARD PRECAUTIONS

Each HIV counseling and testing site should operate under strict universal precautions, following the most recent Occupational Safety and Health Administration (OSHA) guidance. A post-exposure plan should be developed with each organization's medical director. Persons working with sample collection should be vaccinated for Hepatitis A and B. Organizations should have procedures for training all employees on universal precautions, blood borne pathogens, blood/body fluid spill cleanup, the agency's post-exposure plan and where to find it.

Counseling and Testing Schedule:

It is important that WDH staff know when HIV counseling and testing services are offered at any site using materials provided by the State. Please notify the Communicable Disease Prevention Program Manager, with the hours counseling and testing services are available and anytime your site conducts special HIV counseling and testing events.

Quality Control:

All publicly funded HIV counseling and testing sites must adhere to the quality control measures outlined in the Clearview Complete HIV 1 / 2 Product Insert. Historical quality control documents must be readily available during site visits. HIV testing quality control documents should be kept for a comparable amount of time as other clinic records.

Recommended Materials:

- Brochures related to test kit (located in test kit box) – Clearview Complete HIV 1 / 2
- Brochures specific to HIV, STDs and hepatitis can be ordered through the CDU- (*http://www.health.wyo.gov/phsd/cds/index.html*)
- Referral information for other services- mental health, sexual health, substance abuse, health insurance navigation, primary care, sexual assault, intimate partner violence, stalking, Communicable Disease Treatment Program, etc.

Testing Technologies:

- **Rapid Testing**

The Program currently uses the Clearview Complete HIV 1 / 2 test kit distributed by Alere Pharmaceutical. Testing approval is site specific and requires the site to obtain a CLIA Waiver. If this test is reactive, a serum sample is collected for confirmatory testing. Please refer to the Positive Results Protocol for the most recent testing algorithm.

- **Serum Sample**

Serum specimens are required for confirmatory HIV testing and allow for testing of high risk individuals for other infections, such as hepatitis and syphilis. Rapid HIV testing should not be performed if a serum sample cannot be obtained immediately in the event of a reactive result. It is the clinic's responsibility to ensure availability of this service. Please refer to the HIV Positive Test Result Protocol for more detailed instructions on confirmatory sample collection and submission.

TEST RESULTS

Non-Reactive Rapid HIV Test Results

A non-reactive (NR) test result means HIV 1 / 2 antibodies were not detected. Most infected persons will develop detectable HIV antibodies a couple of weeks to months after infection. Because it is likely that an NR test truly indicates the absence of infection, a NR test should seldom be repeated for clients at low risk. For clients with a recent possible exposure to HIV (within the last 6 months) who are tested within this "window period", HIV cannot be definitively excluded without follow-up HIV testing. Provide the client with a timeframe to repeat testing. Whenever possible, the appointment should be set before the client leaves. Repeat testing for clients who exhibit risks should follow the CDC's recommendations on risk based screening. These clients should receive additional risk reduction counseling to prevent possible transmission until their follow up test outside of the window period.

Indeterminate HIV Test Results

Occasionally, a rapid HIV test will present results that are neither reactive nor non-reactive, which is recorded as Indeterminate or Invalid (I) result. The rapid test may be repeated immediately following an indeterminate/invalid result. Clinics should reference the test kit package insert for possible causes and presentations of an indeterminate/invalid result.

Reactive Rapid HIV Antibody Test Results

Please refer to the Positive HIV Test Result Protocol.

Positive HIV Confirmatory Test Results

Please refer to the Positive HIV Test Result Protocol.

GIVING RESULTS

Ideally, each person tested for HIV antibodies at counseling and testing sites should be provided the results in person from the same counselor who collected the sample. ***ALL POSITIVE TEST RESULTS MUST BE GIVEN IN PERSON.*** Results should not be given in the presence of a client's friend, significant other, parent, etc. without first speaking to the client in private to get their freely given consent for other parties to join. Contact the CDU if you are unable to notify a client in person.

Sites may develop internal protocols to notify persons testing negative by other means of notification. Those protocols must be approved by the Communicable Disease Prevention Program Manager prior to implementation.

Personal presentation of the test results is preferred because:

- There is less potential to compromise the individual's privacy
- Permits the counselor to assess the individual's emotional reaction and provides an opportunity for a private and sensitive explanation of the test result's implications
- Allows for discussion of potential infectiousness to others and the importance of providing information to those who may have been exposed
- Provides a person with a reactive test the opportunity to ask questions and receive materials relating to their care and next steps
- Permits a person at risk for HIV infection that has a negative result to discuss risk and or harm reduction strategies
- Provides the counselor an opportunity to make referrals to appropriate services and recommendations for follow-up testing

PARTNER COUNSELING AND REFERRAL SERVICES

The CDC requires all State HIV Prevention Programs to have operational guidelines for Partner Counseling and Referral Services. The Program must make a good faith effort to identify and contact persons who may have been exposed to HIV by positive clients. Specially trained individuals known as Disease Intervention Specialists (DIS) employed by WDH initiate interviews and field investigations to assist those who may have been exposed to HIV. DIS will make appropriate referrals for other services which may be

useful, i.e. Communicable Disease Treatment Program, substance abuse counseling or treatment, mental health, domestic violence counseling, medical services, etc. Making contact and appropriate referrals is also known as Partner Services. Counseling and testing sites that wish to perform their own interviews and investigations must obtain written permission from the Communicable Disease Prevention Program Manager and complete training through the CDC.

Partner Services are available through all state health departments and work cooperatively across state jurisdictions to follow-up with contacts or partners who may reside in other areas. These services are strictly confidential and no "source" names are given to identified contacts.

Any questions related to Partner Services should be referred to the Communicable Disease Prevention Program Manager.

FOLLOW-UP SERVICES

Partner notification, as well as any other appropriate referrals, will be provided for all HIV positive individuals. All HIV positive individuals should be counseled about partner notification and protecting future partners from infection. A DIS will interview the client for information regarding their self-identified sex and/or needle sharing partners. When appropriate, the HIV counselor should take notes about possible partner contacts to give to the DIS. *However, it is not the responsibility of the HIV counselor to contact partners.* If possible, a DIS will be on site when positive confirmatory results are given. This enables the DIS to compile contact lists after a positive result is given. Clients are often more likely to disclose soon after receiving their test results, so it is important to initiate Partner Services as soon as possible.

REFERRALS

For infected clients and those not infected, but at increased risk for HIV, linkage to appropriate medical, prevention, and other supportive services reduces the risk of acquiring or transmitting HIV.

All publicly sponsored counseling and testing sites are expected to keep an accurate and current list of local or regional referral sources for the following referral needs and document referrals as applicable:

- Medical evaluation, care, and treatment (particularly low-cost options)
- Sexual health services
- Drug or alcohol prevention and treatment
- Mental health services
- Screening and treatment for viral hepatitis and tuberculosis
- Sexual assault, intimate partner violence, and stalking

HIV counseling and testing sites work closely with the Ryan White Part B and Part C Programs to ensure that clients who test positive for HIV can quickly enroll in care. Case management services are provided in most public health nursing offices. An up-to-date list can be found at: *http://www.health.wyo.gov/phsd/howpa/forms.html*

QUALIFICATIONS FOR HIV TESTING COUNSELORS

Counselors may be paid staff or volunteers. Both paid staff and volunteer counselors at publicly sponsored sites providing counseling and testing must have successfully completed the WDH Rapid Testing & Counseling Certification class. All certified counselors are strongly encouraged to participate in training updates.

QUALIFICATIONS FOR PUBLICLY SPONSORED HIV TEST SITES

Organizations may apply to the WDH Communicable Disease Prevention Program Manager to become an approved testing and counseling site. Preference will be given to organizations who demonstrate capacity to work with high-risk clientele. The following are some of the criteria used to evaluate a site:

- Staff/organizational capacity to provide services
- Existence of organizational medical director/health officer
- Organizational reputation with high-risk clientele
- Americans with Disabilities Act compliance
- Hours of operation/availability to clientele
- Ability to provide confidential services
- Current CLIA Certificate of Waiver
- PRISM data entry

All liability falls under the testing organization.

EVALUATION PROCESS FOR APPROVED SITES

The WDH publicly sponsored HIV Counseling and Testing Sites will be evaluated in the following manner:

- The Communicable Disease Prevention Program will conduct regular quality assurance on reported HIV tests to assess compliance with guidelines outlined in this protocol. More in-depth, on-site evaluation may be prompted by frequent mistakes, inconsistencies, false reporting, and formal complaints.

- HIV testers and counselors may be required to participate in yearly counselor updates when sponsored by WDH. Evaluations of counseling and testing sessions will be performed by CDU staff as needed.

COUNSELING CONSIDERATIONS IN SPECIAL SITUATIONS

•**Occupational Exposures: Publicly funded HIV tests may not be used to test individuals with occupational exposures.** Testing after occupational exposure is the employer's responsibility and should be evaluated by a licensed healthcare professional who is able to assess for and prescribe post-exposure prophylaxis (PEP).

Although HIV infection following occupational exposure occurs infrequently, workers should be counseled after an occupational exposure to help prevent potential transmission during the follow-up period. HIV-exposed healthcare workers should be advised to abstain from sex or use condoms; avoid pregnancy; not to donate blood, plasma, organs, tissue, or semen. If the exposed healthcare worker is breast feeding, discuss consideration of discontinuing breastfeeding, especially following high-risk exposures. The worker should also be told about the rationale for PEP, the risk for occupationally-acquired HIV infection, the limitations of current knowledge of the efficacy of antiretroviral therapy when used as PEP, the toxicity of the drugs involved, and the need for post-exposure follow-up (including HIV testing), regardless of whether antiretroviral therapy is taken.

•**Persons with a single, recent non-occupational HIV exposure.** After a reported sexual, injecting drug use, or other non-occupational exposure to HIV, healthcare providers should give their clients referrals to promptly initiate evaluation, counseling, and follow-up services. While the window to initiate PEP may have passed, this is still a critical time for other behavioral and biomedical interventions.

•**Sexual assault survivors.** Persons seeking an HIV test after a sexual assault should be offered a referral to a private physician for more thorough medical evaluation and follow-up if not already done. If appropriate, advise the patient on the recommended timeline for repeated follow up testing. Additional documentation may be necessary in the instance of legal action and restitution. If the survivor has not reached out to medical, mental health, or legal advocates make referrals as indicated.

•**Minors.** Persons under 18 years of age may receive HIV testing and counseling without the knowledge or consent of their parent(s) or guardian(s). Youth age 13 and older who seek testing freely and without coercion shall receive services in Wyoming. Youth receive their results according to this protocol and results are not shared with the parent(s) or guardian(s) without freely-given, written consent of the adolescent.

•**Persons seeking testing with a friend, partner, family member, etc.** Getting tested with a sexual partner or supportive individual(s) can decrease the anxiety and stigma associated with HIV testing. However, no exceptions will be made to the expectation of confidential intake, risk assessment, and delivering results until consent for the additional parties to join has been obtained free from coercion or duress.

•Sex or needle sharing partners of HIV infected persons. Sex or needle sharing partners of HIV infected persons should be encouraged to have HIV prevention counseling and testing. Sero-discordant partners (one person is HIV infected and the other(s) uninfected) should receive counseling aimed at preventing HIV transmission, including explicit discussion and clarification of any misconceptions about HIV transmission risks associated with specific sexual and/or needle sharing activities. In addition, many HIV discordant couples benefit from ongoing HIV prevention counseling aimed at individual risk reduction, harm reduction, clean works, serosorting/sero-positioning (making decisions about sexual partners and positions based off of known HIV status and associated risk), pre-exposure prophylaxis (PrEP), etc.

•Persons seeking repeat HIV testing. In addition to brief prevention counseling sessions, ongoing HIV prevention counseling aimed at personal risk reduction may be useful for persons seeking repeated HIV testing who continue to engage in behaviors placing them at risk for HIV infection. Repeat testing in the absence of other behavioral changes is an ineffective personal risk reduction strategy. Clients should be encouraged to identify alternative prevention strategies and realistic steps towards those goals.

•Persons with reactive rapid and negative confirmatory results. Repeat rapid HIV testing should be conducted based off of risks.

•Persons with indeterminate HIV test results. Until follow-up test results are available, persons with an indeterminate test result should be provided information about the meaning of the test results. However, HIV prevention counseling should be approached in the same manner as for a person with newly identified HIV infection. Behaviors that minimize the risk for HIV transmission to sex and needle sharing partners should be emphasized, even if the client reports no risk behaviors.

•Persons with current or historical STD infections. Persons with current or past infections with risk factors in common with HIV infection are at an increased risk of contracting HIV. Dependent on risk behaviors, counselors and testers should recommend a testing schedule for clients.

•Persons who use drugs. Persons who inject or use illicit drugs in other ways may be at increased risk for acquiring HIV through unprotected sex or through sharing paraphernalia with an HIV infected partner. Mounting evidence supports the efficacy of community strategies such as methadone maintenance programs, outreach programs, and syringe exchange in reducing new HIV infections among injection drug users. Experts advocate for such strategies, in addition to individual HIV prevention counseling, to persons who inject drugs. Wyoming currently does not have these types of programs, so providing detailed prevention or other harm reduction strategies would be most practical.

Appendix A

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